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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,559	02/04/2002	Bernard Salles	SFR16PCT US	7125

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YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER
WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,559

Applicant(s)

SALLES ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(s).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-11 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 16-17 and 19-20 is/are rejected.
- 7) ☒ Claim(s) 9-11, 15 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. The applicant's Preliminary Amendment has been entered. The applicant's Preliminary Amendment filed on 04 FEB 02 has been entered as paper no. 8 (Amdt. A). Following the entry of the Preliminary Amendment, **Claim(s) 1-6, 9-11 and 15-20** is/are pending.

SPECIFICATION

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

CLAIM OBJECTIONS

3. **Claim(s) 9-11, 15 and 18** is/are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims have not been further considered.

35 USC § 112- 2ND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

5. Claim(s) 1-6, 16-17 and 19 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because of the inconsistency between the use of the phrases comprising on line 2, and "consists in" on line 15. Comprising is open language allowing for the incorporation of other unrecited step(s) and/or reagent(s) while "consist in" is closed language preventing the incorporation of other unrecited step(s) and/or reagent(s). The use of these two transition phrases in Claim 1 makes it unclear if Claim 1 is an open or a closed claim. Claims 2 and Claims 4-6 have the same problem. Please clarify.

Claim 1 is also indefinite because on line 16 the claim recites "causing to act on this damaged DNA". This phrase lacks proper antecedent basis in the 3rd part of the preamble (i.e. "or - treatment of cells, - lysis and capture of cellular DNA,") .

Claim 4 is indefinite because the phrase "after desorption of the complexes by analysis of the immunoblotting type" is non-sequitur.

Claims 5-6 are indefinite because the phrase "the supernatant" on line 3 lacks proper antecedent basis in Claim 4.

Claim 18 is indefinite because the phrase "the adsorbed DNA" on line 3 lacks proper antecedent basis in Claim 1.

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35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

7. **Claim(s) 1-2, 16-17 and 19** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Provot et al. [WO 96/28571(1996)].

Provot et al. teach a process for the detection of damage to DNA comprising all of the limitations recited in Claim(s) 1-2, 16-17 and 19. Note that for this rejection the examiner has relied on US 6,261,727 (2001) as a translation for WO 96/28571(1996).

8. **Claim(s) 1-2, 16-17 and 19** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Provot et al. [US 6,261,727 (2001)].

Provot et al. teach a process for the detection of damage to DNA comprising all of the limitations recited in Claim(s) 1-2, 16-17 and 19.

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35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

11. Claim(s) 3 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Provot et al. [US 6,261,727 (2001)] as applied against Claim 1 above and further in view of Engelhardt et al. [US 5,241,060 (1993)].

Provot et al. teach a process for the detection of damage to DNA comprising all of the limitations recited in Claim(s) 3 except these authors do not explicitly teach using primary and secondary antibodies. However as evidenced by Engelhardt et al., the use of primary and secondary antibodies to detect an antigen was well known at the time of the invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Provot et al. with the primary and secondary antibodies of Engelhardt et al. Absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

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12. Claim(s) 20 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Provot et al. [US 6,261,727 (2001)] as applied against Claim 1 above and further in view of the Stratagene Catalog (1998).


Provot et al. teach a process for the detection of damage to DNA which utilizes all of the reagents recited in Claim 20. These authors do not explicitly teach placing the reagents for performing their method into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the teachings of Provot et al. with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method taught by Provot et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

CONCLUSION

13. Claim(s) 1-6, 9-11 and 15-20 is/are rejected and/or objected to for the reason(s) set forth above.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.


Ethan Whisenant, Ph.D.
Primary Examiner